AnPac Bio Class III Medical Device Passes Extensive NMPA Registration Tests and Will Start Clinical Trial in Q1, 2022

January 4, 2022

PHILADELPHIA, Jan. 04, 2022 (GLOBE NEWSWIRE) -- AnPac Bio-Medical Science Co., Ltd. (“AnPac Bio,” the “Company” or “we”) (ANPC), a US and China-based biotechnology company focused on early cancer screening and detection, announced today that on December 30, 2021, the Company's Class III medical device for lung cancer auxiliary diagnosis has completed and passed stringent and rigorous registration tests at the testing laboratory designated by the National Medical Products Administration (NMPA), China’s regulatory agent for medical products. China’s extensive Class III medical device registration tests included medical device performance tests related to accuracy, precision, stability, linearity, accuracy and repeatability in sample addition, cross-contamination, electromagnetic compatibility (EMC), and reliability and performance under various environmental conditions. Completion of the NMPA registration tests is a significant milestone toward obtaining a Class III medical device registration certificate. Following completion of the registration test, the remaining major step prior to final approval of a registration certificate will be clinical trials which will begin in the first quarter of 2022 with two qualified clinical trial medical institutions.

AnPac Bio began its official medical device registration process in December 2018 by filing an application for medical device classification with the NMPA. Since then, AnPac Bio has obtained the determination of the product classification (recommended as Class III) from the NMPA, carried out significant medical device optimization, completed rigorous internal medical device testing, undergone extensive external third-party testing and validation, and received a certificate of designated inspection capability from the designated medical device registration test laboratory.

The above-mentioned Class III medical device designation is based on AnPac Bio’s novel cancer differentiation analysis (CDA) technology, which has been used in cancer risk assessment tests for general population and clinical studies and has already accumulated more than 240,000 samples including general population screening, as well as extensive retrospective and prospective clinical studies with leading medical institutions. If AnPac Bio is successful in obtaining the Class III registration certificate from the NMPA for its CDA device, it will add additional markets and channels for the Company to sell its tests. AnPac Bio will be able to penetrate the medical segment of the market, including hospitals and medical institutions for lung cancer auxiliary diagnosis tests, which is a significant market, and can further fuel the Company’s revenue growth.

Dr. Chris Yu, CEO and Chairman of AnPac Bio commented: “We are very excited about this significant milestone and major accomplishment. By passing this challenging and rigorous medical device registration test, we have demonstrated our technical and commercialization capabilities. Lung cancer is a major cancer and there are very few approved registration certificates for lung cancer, so obtaining a Class III medical device registration certificate for lung cancer auxiliary diagnosis would enhance our competitive position in the marketplace and position us for increased revenues. This is one of AnPac Bio’s most important projects, along with our plan to commercialize and market our CDA test as a laboratory developed test (LDT) in the United States. We now expect significant further progress in obtaining Class III medical device registration certificate in China and LDT in the US in 2022.”

About AnPac Bio
AnPac Bio is a biotechnology company focused on early cancer screening and detection, with 150 issued patents as of September 30, 2021. With two certified clinical laboratories in China and one CLIA and CAP accredited clinical laboratory in the United States, AnPac Bio performs a suite of cancer screening and detection tests, including CDA (Cancer Differentiation Analysis), bio-chemical, immunological, and genomics tests. According to Frost & Sullivan, AnPac Bio ranked third worldwide among companies offering next-generation early cancer screening and detection technologies in terms of the number of clinical samples for cancer screening and detection, based on approximately 43,980 clinical samples as of September 30, 2021. AnPac Bio’s CDA technology platform has been shown in retrospective validation studies to be able to detect the risk of over 20 different cancer types with high sensitivity and specificity.

For more information, please visit: https://www.Anpacbio.com.

For investor and media inquiries, please contact:

Company:
Phil Case, Marketing and Investor Relations
Phone: +1-267-810-6776 (US)
Email: phil_case@AnPacbio.com

Investor Relations:
Ascent Investor Relations LLC
Tina Xiao, President
Phone: +1-917-609-0333 (US)
Email: tina.xiao@ascent-ir.com

Safe Harbor Statement

This announcement contains 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. These forward-looking statements are made under the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995 and are relating to the Company's future financial and operating performance. The Company has attempted to identify forward-

looking statements by terminologies including "believes," "estimates," "anticipates," "expects," "plans," "projects," "intends," "potential," “target,” “aim,” “predict,” “outlook,” “seek,” “goal” “objective,” “assume,” “contemplate,” “continue,” “positioned,” “forecast,” “likely,” "may," "could," "might," "will," "should," "approximately" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. These statements are based on current expectations, assumptions and uncertainties involving judgments about, among other things, future economic, competitive and market conditions and future business decisions, all of which are difficult or impossible to predict accurately and many of which are beyond the Company's control. These statements also involve known and unknown risks, uncertainties and other factors that may cause the Company's actual results to be materially different from those expressed or implied by any forward-looking statement. Known and unknown risks, uncertainties and other factors include, but are not limited to, the implementation of our business model and growth strategies; trends and competition in the cancer screening and detection market; our expectations regarding demand for and market acceptance of our cancer screening and detection tests and our ability to expand our customer base; our ability to obtain and maintain intellectual property protections for our CDA technology and our continued research and development to keep pace with technology developments; our ability to obtain and maintain regulatory approvals and registration certificates from the NMPA, the FDA and the relevant U.S. states and have our laboratories certified or accredited by authorities including the CLIA; our future business development, financial condition and results of operations and our ability to obtain financing cost-effectively; potential changes of government regulations; general economic and business conditions in China and elsewhere; our ability to hire and maintain key personnel; our relationship with our major business partners and customers; and the duration of the coronavirus outbreaks and their potential adverse impact on the economic conditions and financial markets and our business and financial performance, such as resulting from reduced commercial activities due to quarantines and travel restrictions instituted by China, the U.S. and many other countries around the world to contain the spread of the virus. Additionally, all forward-looking statements are subject to the “Risk Factors” detailed from time to time in the Company's most recent Annual Report on Form 20-F and other filings with the U.S. Securities and Exchange Commission. Because of these and other risks, uncertainties and assumptions, undue reliance should not be placed on these forward-looking statements. In addition, these statements speak only as of the date of this press release and, except as may be required by law, the Company undertakes no obligation to revise or update publicly any forward-looking statements for any reason.