Qorvo® Biotechnologies Receives FDA Emergency Use Authorization (EUA) for Rapid COVID-19 Antigen Testing

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GREENSBORO, N.C., April 15, 2021 (GLOBE NEWSWIRE) -- Qorvo® (Nasdaq: QRVO), a leading provider of innovative radio frequency (RF) solutions that connect the world, today announced that the U.S. Food and Drug Administration (FDA) has granted emergency use authorization (EUA) for the Qorvo Omnia™ SARS-CoV-2 Antigen Test. The test is authorized for the qualitative detection of nucleocapsid viral antigens from SARS-CoV-2 in nasal swab specimens from individuals who are suspected of COVID-19.

The Qorvo Omnia platform represents a paradigm shift in diagnostic testing capability by using high frequency Bulk Acoustic Wave (BAW) sensors to achieve SARS-CoV-2 (COVID-19) antigen testing in approximately 20 minutes. BAW sensor technology enables low Limit of Detection (LOD) levels that are similar to molecular testing capability.

The Qorvo Omnia platform features a portable test instrument, microfluidic cartridge and secure connectivity. The microfluidic cartridge design enables specific binding with additional wash steps similar to central lab instrument operation and demonstrated results including 100% specificity during clinical trials.

Fred S. Apple, Ph.D., a member of Qorvo Biotechnologies' advisory board, Co-Medical Director of Toxicology Laboratory at Hennepin Healthcare/Hennepin County Medical Center, and Professor of Laboratory Medicine & Pathology at the University of Minnesota, said, "This is very exciting news. FDA authorization of Qorvo's Omnia Antigen Test provides a rapid, sensitive and specific assessment of individuals, assisting providers trying to either rule in or rule out COVID-19, comparable to many of the PCR testing platforms in use. The testing system will hopefully be an avenue to assist in opening up the United States to be closer to business as usual."

James Klein, President of Qorvo Biotechnologies, said, "The FDA's EUA is recognition that the Qorvo Omnia platform can help address the ongoing need for rapid, accurate and clinically-reliable diagnostic testing. We are honored to leverage Qorvo's technology portfolio to help public health officials respond to this global pandemic."

For more information, visit www.qorvobiotech.com.

The Qorvo Omnia SARS-CoV-2 Antigen Test has not been FDA cleared or approved. It has been authorized by the FDA under an Emergency Use Authorization and testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform moderate or high complexity tests. This test has been authorized only for the detection of proteins from SARS-CoV-2, not for any other viruses or pathogens. These tests are only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

About Qorvo Biotechnologies
Qorvo Biotechnologies, LLC is a wholly owned subsidiary of Qorvo, Inc. focused on the development of point-of-care (POC) diagnostics solutions leveraging Qorvo's innovative BAW sensor technology.

About Qorvo
Qorvo (Nasdaq: QRVO) makes a better world possible by providing innovative Radio Frequency (RF) solutions at the center of connectivity. We combine product and technology leadership, systems-level expertise and global manufacturing scale to quickly solve our customers' most complex technical challenges. Qorvo serves diverse high-growth segments of large global markets, including advanced wireless devices, wired and wireless networks and defense radar and communications. We also leverage unique competitive strengths to advance 5G networks, cloud computing, the Internet of Things, and other emerging applications that expand the global framework interconnecting people, places and things. Visit www.qorvo.com to learn how Qorvo connects the world.

Investor Relations Contact: Doug DeLieto VP, Investor Relations W +1-336-678-7968	**Media Contact:** Brent Dietz Qorvo Director of Corporate Communications W + 1 336-338-2711 brent.dietz@qorvo.com

This press release includes "forward-looking statements" within the meaning of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, but are not limited to, statements about our plans, objectives, representations and contentions, and are not historical facts and typically are identified by use of terms such as "may," "will," "should," "could," "expect," "plan," "anticipate," "believe," "estimate," "predict," "potential," "continue" and similar words, although some forward-looking statements are expressed differently. You should be aware that the forward-looking statements included herein represent management's current judgment and expectations, but our actual results, events and performance could differ materially from those expressed or implied by forward-looking statements. We do not intend to update any of these forward-looking statements or publicly announce the results of any revisions to these forward-looking statements, other than as is required under U.S.

federal securities laws. Our business is subject to numerous risks and uncertainties, including those relating to fluctuations in our operating results; our substantial dependence on developing new products and achieving design wins; our dependence on a few large customers for a substantial portion of our revenue; a loss of revenue if contracts with the United States government or defense and aerospace contractors are canceled or delayed or if defense spending is reduced; the COVID-19 pandemic, which has and will likely continue to negatively impact the global economy and disrupt normal business activities, and which may have an adverse effect on our results of operations; our dependence on third parties; risks related to sales through distributors; risks associated with the operation of our manufacturing facilities; business disruptions; poor manufacturing yields; increased inventory risks and costs due to timing of customer forecasts; our inability to effectively manage or maintain evolving relationships with platform providers; risks from international sales and operations; economic regulation in China; changes in government trade policies, including imposition of tariffs and export restrictions; our ability to implement innovative technologies; underutilization of manufacturing facilities as a result of industry overcapacity; we may not be able to borrow funds under our credit facility or secure future financing; we may not be able to generate sufficient cash to service all of our debt; restrictions imposed by the agreements governing our debt; volatility in the price of our common stock; damage to our reputation or brand; fluctuations in the amount and frequency of our stock repurchases; our recent and future acquisitions and other strategic investments could fail to achieve financial or strategic objectives; our ability to attract, retain and motivate key employees; our reliance on our intellectual property portfolio; claims of infringement of third-party intellectual property rights; security breaches and other similar disruptions compromising our information; theft, loss or misuse of personal data by or about our employees, customers or third parties; warranty claims, product recalls and product liability; and risks associated with environmental, health and safety regulations and climate change. Many of the foregoing risks and uncertainties are, and will continue to be, exacerbated by the COVID-19 pandemic and any worsening of the global business and economic environment as a result. These and other risks and uncertainties, which are described in more detail in Qorvo's most recent Annual Report on Form 10-K and in other reports and statements filed with the Securities and Exchange Commission, could cause actual results and developments to be materially different from those expressed or implied by any of these forward-looking statements.