Quotient Limited Announces Receipt of U.S. FDA Emergency Use Authorization (EUA) for MosaiQ COVID-19 Antibody Test

JERSEY, Channel Islands, 28 September 2020 (GLOBE NEWSWIRE) -- Quotient Limited (NASDAQ:QTNT), headquartered in Eysins, Switzerland, today announced that on September 25, 2020, the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for Quotient's COVID-19 antibody test. The test detects antibodies generated in humans in response to the SARS-CoV-2 virus using Quotient's proprietary MosaiQ blood testing microarray technology. The antibody test was CE marked on May 1, 2020 and is now available in Europe and the US.

As previously announced, Quotient has entered into contracts to supply its COVID-19 antibody tests to customers in the U.S. One of those customers, Bloodworks Northwest, is seeking to source convalescent blood plasma taken from donors whose blood contains SARS-CoV-2 virus antibodies, for use in treating COVID-19 patients.

Franz Walt, Quotient's Chief Executive Officer, said "The issuance of the EUA is an important milestone for Quotient, because it is the first MosaiQ test to receive an FDA authorization. Before granting the EUA, the FDA reviewed not only our COVID-19 antibody test but also the MosaiQ Instrument and related software. Now that the innovative and novel MosaiQ technology has gone through the FDA review process, we are optimistic about the prospects for future FDA approvals of the other Quotient blood testing products in our pipeline. These products are all based on the same MosaiQ technology platform."

Further independent external evaluations of Quotient's COVID-19 antibody test

Quotient believes customers find its COVID-19 antibody tests attractive because they are highly accurate and the MosaiQ system is efficient. The test is performed on Quotient's fully automated, high-throughput MosaiQ instrument. A single MosaiQ testing instrument can process up to 3,000 antibody tests per day. Independent studies continue to confirm that Quotient's MosaiQ COVID-19 antibody testing system is highly accurate and efficient. In the September issue of the Journal of Clinical Virology, the Medical Laboratory of the French Military and the French Military Biomedical Research Institute published an independent, external study evaluating the MosaiQ COVID-19 Antibody Microarray and MosaiQ system. It concluded that the clinical specificity of the test is 100%, and the sensitivity was over 98% in samples taken more than 14 days after the onset of COVID-19 symptoms. The evaluation also concluded that the MosaiQ system "enabled rapid throughput of samples, and the single-use microarray is of specific interest to manage high numbers of samples in a limited time with low levels of laboratory technician support." Recent results from an independent, third-party study evaluation in Scotland also confirmed the high-performance attributes of the MosaiQ COVID-19 Antibody Microarray.

About Quotient Limited

Building on over 30 years of experience in transfusion diagnostics, Quotient is a commercial-stage diagnostics company committed to delivering solutions that reshape the way diagnostics is practiced. MosaiQ, Quotient's

proprietary multiplex microarray technology, offers the world's first fully automated, consolidated testing platform, allowing for multiple tests across different modalities. MosaiQ is designed to be a game-changing solution, which Quotient believes will increase efficiencies, improve clinical practice, deliver significant workflow improvements, and operational cost savings to laboratories around the world. A serological test was developed in April 2020 in response to the global COVID-19 pandemic. The MosaiQ COVID-19 Antibody Microarray is CE marked and is the subject of an Emergency Use Authorization issued by the U.S. Food and Drug Administration. The COVID-19 antibody test is available for distribution in the U.S., the EU, the UK and Switzerland. Quotient's operations are based in Eysins, Switzerland, Edinburgh, Scotland and Newtown, Pennsylvania.

Forward-Looking Statements

This news release 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 and the Private Securities Litigation Reform Act of 1995. These forward-looking statements may include statements regarding our expectations of continued growth, the development, regulatory approval, commercialization and impact of MosaiQ and other new products (including the potential for using our MosaiQ technology to test for COVID-19 antibodies). Such statements are based on current assumptions that involve risks and uncertainties that could cause actual outcomes and results to differ materially. These risks and uncertainties, many of which are beyond our control, include delays or denials of regulatory approvals or clearances for products or applications; market acceptance of our products; the impact of competition; the impact of facility expansions and expanded product development, clinical, sales and marketing activities on operating expenses; delays or other unforeseen problems with respect to manufacturing, product development or field trial studies; adverse results in connection with any ongoing or future legal proceeding; continued or worsening adverse conditions in the general domestic and global economic markets, including the recent novel coronavirus (COVID-19) outbreak; as well as the other risks set forth in the Company's filings with the Securities and Exchange Commission. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Quotient disclaims any obligation to update these forward-looking statements.

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