Quotient Limited Provides Status Update on the Initial SDS Microarray and MosaiQ Instrument for the US Market

JERSEY, Channel Islands, 10 December 2020 (GLOBE NEWSWIRE) --Quotient Limited (NASDAQ:QTNT), a commercial-stage diagnostics company (the Company), today announced that it received a request from the U.S. Food and Drug Administration (FDA) for additional testing data regarding the 510(k) application for the Initial Serological Disease Screening Microarray (SDS) and MosaiQ instrument. The data the FDA has requested relates to specific individual performance characteristics of the assays on the microarray. In response to this request, the Company intends to re-submit its application, with the additional data requested by the FDA, in early 2021. Following that submission, the Company is targeting to receive the FDA 510(k) clearance in mid-2021.

The Company does not expect to be materially impacted by the need to submit additional data. Franz Walt, Chief Executive Officer of Quotient, explained "We do not expect this development will delay the commercial launch of our MosaiQ platform in the US. As we always said, the commercialization of the initial SDS will only commence once the expanded Immunohematology microarray is available."

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. In response to the global effort to combat COVID-19, Quotient developed the MosaiQ COVID-19 Antibody Microarray which is CE marked and has received the U.S. FDA Emergency Use Authorization. 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, 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 the underwritten public offering, including the anticipated net proceeds to be raised in the offering and expected closing date of the offering. Such statements are based on current assumptions that involve risks and uncertainties that could cause actual outcomes and results to differ materially, including: market conditions; Quotient's ability to satisfy closing conditions related to the offering; unanticipated expenses associated with the offering; and other risks set forth in Quotient's most recent Annual Report on Form 10 K and Quarterly Report on Form 10 Q, as well as other documents that Quotient files with the Securities and Exchange Commission, including the Registration Statement on Form S 3 (File No. 333 248235), as amended by Amendment No. 1, for the offering. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only

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