TransMedics Announces Temporary Postponement of OCS Heart FDA Advisory Panel Committee Meeting Due to COVID-19 Emergency

March 17, 2020

ANDOVER, Mass., March 17, 2020 (GLOBE NEWSWIRE) -- TransMedics Group, Inc. (“TransMedics”) (Nasdaq: TMDX), a medical technology company that is transforming organ transplant therapy for patients with end-stage lung, heart and liver failure, today announced that the Company and FDA/CDRH have mutually agreed to postpone the originally scheduled April 16th FDA Advisory Committee meeting to review the OCS Heart System due to the national emergency status relating to the COVID-19 Cornavirus. TransMedics and the Office of Cardiovascular Devices at FDA have agreed to continuously monitor the situation and work to reschedule the panel meeting as soon as possible.

“We are disappointed by this unforeseen delay; however, TransMedics, FDA, and the nation are facing current unprecedented challenges and we will do everything possible to act and work collaboratively with the Office of Cardiovascular Devices to hopefully overcome these challenges in the near future,” said Waleed Hassanein, M.D., President and Chief Executive Officer. “We look forward to announcing the revised date of our panel as soon as it is rescheduled.”

About TransMedics Group, Inc.
TransMedics is the world’s leader in portable ex-vivo warm perfusion and assessment of donor organs for transplantation. Headquartered in Andover, Massachusetts, the company was founded to address the unmet need for more and better organs for transplantation and has developed technologies to preserve organ quality, assess organ viability prior to transplant, and potentially increase the utilization of donor organs for the treatment of end-stage heart, lung and liver failure.

Forward-Looking Statements
This press release contains forward-looking statements. Investors are cautioned not to place undue reliance on these forward-looking statements, including statements about our results of operations, commercial opportunity and the rate of adoption and benefits of the OCS. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement. Applicable risks and uncertainties include those related to our anticipation that we will continue to incur losses in the future; our potential need to raise additional funding; our existing and any future indebtedness, including our ability to comply with affirmative and negative covenants under our credit agreement, and our ability to obtain additional financing on favorable terms or at all; the fluctuation of our financial results from quarter to quarter; our ability to use net operating losses and research and development credit carryforwards; our dependence on the success of the OCS; the rate and degree of market acceptance of the OCS; our ability to educate patients, surgeons, transplant centers and private payors of benefits offered by the OCS; our ability to improve the OCS platform; our dependence on a limited number of customers for a significant portion of our net revenue; the timing of and our ability to obtain and maintain regulatory approvals or clearances for our OCS products; our ability to adequately respond to FDA follow-up inquiries in a timely manner; the performance of our third-party suppliers and manufacturers; the timing or results of clinical trials for the OCS; our manufacturing, sales, marketing and clinical support capabilities and strategy; attacks against our information technology infrastructure; the economic, political and other risks associated with our foreign operations; our ability to attract and retain key personnel; our ability to protect, defend, maintain and enforce our intellectual property rights relating to the OCS and avoid allegations that our products infringe, misappropriate or otherwise violate the intellectual property rights of third parties; our expectations for the pricing of the OCS, as well as the reimbursement coverage for the OCS in the United States and internationally; regulatory developments in the United States, European Union and other jurisdictions; the extent and success of competing products that are or may become available; the impact of any product recalls or improper use of our products; our estimates regarding revenues, expenses and needs for additional financing; and the risks identified under the heading “Risk Factors” and elsewhere in the final prospectus dated May 1, 2019 related to our initial public offering, and in our quarterly report on Form 10-Q for the quarter ended September 28, 2019, which are available on the SEC’s website at www.sec.gov. Additional information will be made available by our annual and quarterly reports and other filings that we make from time to time with the SEC. These forward-looking statements (except as otherwise noted) speak only as of the date of this presentation. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We undertake no obligation to update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by applicable law.

Investor Contact:
Brian Johnston
631-807-1986
Investors@transmedics.com

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