TransMedics Announces the Second FDA PMA Approval for its OCS Lung System, Allowing Access to a Larger Pool of Donor Lungs that are Currently Seldomly Utilized for Transplantation Due to Limitations of Cold Storage

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ANDOVER, Mass., June 03, 2019 (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 it has received an FDA PMA approval for expanded clinical indications of the Organ Care System (OCS) Lung. This approval will enable the OCS Lung System to be used for the preservation and ex-vivo assessment of both standard criteria donor lungs as well as the larger pool of donor lungs initially deemed unacceptable for procurement and transplantation based on limitations of cold static preservation. This approval will also enable the OCS Lung System to be used with both donors after brain death (DBD) and donors after circulatory death (DCD). Prior to this latest FDA approval, the OCS Lung System was approved for standard criteria lungs from DBD donors only. Based on this FDA PMA approval, TransMedics will expand its post-market Thoracic Organ Perfusion (TOP) Registry to collect long-term post-market data from recipients of all OCS Lung preserved standard criteria and initially deemed unacceptable donor lungs.

"We are pleased with the FDA approval which uniquely positions the OCS Lung System as the only technology approved for both standard criteria and initially deemed unacceptable donor lungs for transplantation," said Dr. Waleed Hassanein, CEO of TransMedics, Inc. "With this approval, the OCS Lung System could enable a significant increase in donor lung utilization for transplantation in the U.S. from those DBD and DCD donors that were initially deemed unacceptable based on limitations of cold storage. Now, these lungs can be preserved and assessed ex-vivo using our OCS Lung System to determine their suitability for transplantation. This marks a major milestone forward in our drive to expand access to life-saving transplant procedures for patients suffering from end-stage organ failure," said Dr. Hassanein.

"Lung transplant surgeons now have access to a technology that enables preservation and assessment and use of lungs from a wide range of donors. Importantly, the OCS Lung System enables these capabilities from the minute the donor lungs are procured until they are ready to be transplanted into the recipient across wide distances," said Dr. Gabriel Loor, the U.S. Principal Investigators for the OCS Lung EXPAND trial. "This important milestone offers the promise to further expand the number and improve the quality of donor organs for sick patients waiting for lung transplant worldwide," said Prof. Dirk Van Raemdonck the International Principal Investigator for the OCS Lung EXPAND Trial.

The FDA approval is based on the results of the OCS Lung EXPAND pivotal international, multicenter trial that demonstrated safety and effectiveness of TransMedics' OCS Lung System for ex-vivo preservation and assessment of donor lungs from DBD and DCD donors that were initially deemed unacceptable for procurement and for transplantation due to the limitations of cold static preservation.

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 the implications of the PMA approvals and potential market for TransMedics products. 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 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 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; our use of proceeds from our initial public offering; 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, which is available on the SEC's website at www.sec.gov. Additional information will be made available by our quarterly reports on Form 10-Q 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 press release. 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.

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