TransMedics Announces Positive Top Line Results From the U.S. Randomized OCS DCD Heart Trial

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ANDOVER, Mass., Nov. 4, 2021 /PRNewswire/ -- 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 positive topline results from its OCS donors after circulatory death (DCD) Heart Trial.

The OCS DCD Heart Trial was designed as the first and only randomized trial to compare post-transplant clinical outcomes between hearts transplanted from DCD donors that were resuscitated and assessed on OCS Heart System and hearts transplanted from donors after brain death (DBD) that were preserved using the current standard of cold storage in the U.S. The primary goal was to assess the effectiveness and safety of OCS Heart technology to expand the heart donor pool to include DCD donors. Heart transplant candidates were randomized 3:1 into two groups: DCD Heart Possible (DCD) or DBD cold stored hearts (Control). The trial protocol compared the post-transplant outcomes from recipients of DCD hearts preserved on OCS (DCD) to all those who received standard criteria DBD hearts preserved with cold storage (DBD Control).

The OCS DCD Heart trial achieved its primary clinical objectives by meeting the primary effectiveness endpoint of 6 months patient survival post-transplant which was 95% for OCS DCD arm vs. 89% for DBD Control arm. Even when the outcomes were adjusted for all risk factors between the two groups the results were 94% for OCS and 90% for Control (non-inferiority $p<0.0001$). Of 101 DCD donor hearts that were perfused and assessed on OCS Heart technology, 90 were successfully transplanted resulting in a utilization rate of 89%. Long-term followup is ongoing and the final results will be presented at the upcoming Scientific Meeting of the International Society for Heart and Lung Transplantion in April 2022.

The OCS Heart System was approved by the U.S. Food and Drug Administration (FDA) for its DBD heart indication in September 2021. These OCS DCD Heart trial results will be submitted shortly to FDA in a PMA supplement to support the approval for the OCS DCD heart indication.

"The OCS DCD Heart Trial provides objective randomized evidence showing high utilization and excellent short-term clinical outcomes using hearts that historically were never considered for transplants in the U.S.," said Dr. Jacob Schroder, surgical director of heart transplantation at Duke University Medical Center and the principal investigator for the OCS DCD Heart Trial. "The more widespread use of DCD hearts for transplantation is the biggest thing to happen since the beginning of heart transplantation!"

"These results are tremendously exciting and confirm our belief that the OCS Heart System is a transformative technology that allows us to safely utilize donor organs that were previously never considered," said Dr. David D'Alessandro, surgical director of heart transplantation at Massachusetts General Hospital and the co-principal investigator for the OCS DCD Heart Trial. "We now have a unique technology which will allow us to offer this life saving therapy to more patients than ever before."

"These clinical results are transformative to the field of heart tranplantation. The trial met and exceeded the very high bar of comparing transplant clinical outcomes of OCS DCD heart to standard criteria DBD heart in the U.S., which are known to be the best in the world," said Waleed Hassanein, MD, President and Chief Executive Officer. "This will have a far reaching positive impact on increasing access to life-saving heart transplants to patients in need. We are very grateful for all the donor families, trial investigators, their teams, and institutions for completing this seminal trial in heart transplantation."

About TransMedics Group, Inc.

TransMedics is the world's leader in portable extracorporeal 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 with respect to future events, including the commercialization and market opportunity of the OCS Heart. These forward-looking statements are subject to a number of risks, uncertainties and assumptions. Moreover, we operate in a very competitive and rapidly changing environment and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in or implied by any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this press release may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Some of the key factors that could cause actual results to differ include: that we continue to incur losses; our 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 to which we will remain subject to until maturity, and our ability to obtain additional financing or refinance existing indebtedness 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[, including our efforts to develop a national OCS program]; our ability to educate patients, surgeons, transplant centers and private and public payors of benefits offered by the OCS; the impact of the outbreak of the novel strain of coronavirus and associated containment, remediation and vaccination efforts; our ability to improve the OCS platform and to develop the next generation of our OCS technology 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 timing of and our ability to commercialize and market our OCS products; the performance of our third-party suppliers and manufacturers; the timing or results of post-approval studies any any 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; the pricing of the OCS, as well as the reimbursement coverage for the OCS in the United States and internationally; regulatory developents in the United States, Europeon 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 use of proceeds from our equity offerings; our estimates regarding revenues, expenses and needs for additonal financing; and the risks identified under the heading "Risk Factors" and elsewhere in our annual report on Form 10-K for the year ended December 31, 2020, our quarterly reports on Form 10-Q and in any subsequent filings with the Securities and Exchange Commission ("SEC"). 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 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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