TransMedics Announces Positive FDA Advisory Committee Vote for OCS Heart System

Panel votes 12 to 5 that benefits of OCS Heart System outweigh risks

Andover, Mass. – April 6, 2021 – 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, announced today that after the review of TransMedics' clinical evidence from the OCS Heart EXPAND trial, the associated Continued Access Protocol ("CAP") results, as well as the OCS Heart PROCEED II trial, the Circulatory Systems Device Advisory Panel convened by the U.S. Food and Drug Administration ("FDA") has issued a favorable vote in support of approval of the OCS Heart System to the FDA's Office of Health Technology 2 (Cardiovascular Devices). The panel voted 12 to 5, with 1 abstaining, that the benefits of the OCS Heart System outweigh its risks. The panel voted 10 to 6, with 2 abstaining, that there is reasonable assurance that the OCS Heart System is effective. The panel voted 9 to 7, with 2 abstaining, that there is reasonable assurance of the OCS Heart System's safety.

FDA Advisory Committees provide the FDA with independent opinions and non binding recommendations from outside medical experts. While the FDA will consider the opinions and recommendations expressed at the Advisory Committee, the FDA will make a decision regarding whether to approve the premarket approval application for the use of the OCS Heart System for donor hearts currently utilized and unutilized for transplantation after completion of its review of the application.

"This is a critical milestone for the OCS Heart technology on the path to a potential FDA approval, which I am confident would benefit patients in need of heart transplantation in the U.S. We are looking forward to working collaboratively with the FDA as it completes its review," said Waleed Hassanein, MD, President and Chief Executive Officer. "We are grateful for the help and support of our investigators, the patients who enrolled in our trials, and the donor families who gave our patients the gift of life by supporting organ donation. In addition, we want to thank the respected members of the Advisory Panel and the FDA review team for their thoughtful discussion and deliberations on this important PMA. We are now laser focused and looking forward to our next important business milestones planned for 2021: the scheduling the OCS Liver FDA Advisory Panel Meeting, the final readout of the OCS Heart DCD trial and the filing of the DCD Heart PMA supplement to eventually expand our OCS Heart indication into DCD heart transplantation in the U.S."

"For decades we have talked about heart transplant being supply limited. If approved by the FDA, with the use of OCS Heart System for extended criteria donors, and DCD hearts, we can access to a significantly greater suitable donor poll, said Dr. Jacob Schroder, surgical director of heart

transplantation at Duke University Medical Center and the principal investigator for the OCS Heart EXPAND Trial. “As the donor pool expands, more patients can have access to this life saving therapy. If the OCS Heart System is approved, I believe the industry will reverse its thinking and open up the ‘demand’ to a greater patient population that never had a chance at a new heart and a better life.”

"The potential opportunity to expand the donor pool for our heart transplant candidates using the TransMedics device in select patients would be a major advance in the field of heart transplantation,” said Dr. Maryjane Farr, medical director of the transplant program at Columbia University Irving Medical Center.

EXPAND and CAP Trial

The OCS Heart EXPAND trial met its primary effectiveness endpoint. It showed that the use of the OCS Heart System resulted in successfully transplanting 84% - more than 8 out 10 of the extended-criteria donor hearts that are seldom used for transplant today in the U.S. using cold ischemic storage preservation. The post-transplant rate of severe Primary Graft Dysfunction was 8%, which is well below the rates reported in the literature and there were no unexpected safety findings. Patient survival at 30-days post-transplant was 97%. All-cause survival was 92% at 6 months and 87% at 12 months. Importantly, cardiac-related survival was 96% at both 6 and 12 months, these survival rates are comparable to U.S. standard heart transplant outcomes.

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 those that affect potential regulatory approvals for our OCS Heart System. 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 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; the impact of the outbreak of the novel strain of coronavirus and associated containment and remediation efforts; 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 ability to obtain and maintain regulatory approvals or clearance for our OCS products; the pricing of the OCS, as well as the reimbursement coverage for the OCS in the United States and internationally; 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, 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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