TransMedics Receives FDA PMA Approval of OCS™ DCD Heart Indication

April 28, 2022

ANDOVER, Mass., April 28, 2022 /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 that the U.S. Food and Drug Administration (FDA) has granted premarket approval (PMA) of its OCS™ Heart System for use with organs from donors after circulatory death (DCD). The landmark approval stands to significantly expand the pool of eligible donor hearts in the United States and follows FDA PMA approval of the OCS™ Heart System for use with organs from donors after brain death (DBD) received in September 2021.

The OCS™ Heart System is now approved with the extended clinical indication for ex vivo reanimation, functional monitoring, and beating-heart preservation of donation-after-circulatory-death (DCD) hearts. This indication is based on the results of the OCS™ DCD Heart Trial and the associated Continued Access Protocol (CAP). Final and long-term results from the trial will be unveiled on Friday, April 29th at the ongoing International Society of Heart and Lung Transplantation (ISHLT) 2022 Annual Meeting in Boston, MA.

"The FDA's approval of the OCS for DCD donor hearts is the natural progression from the prior approval of the device for extended criteria brain dead donors, supported by the excellent results from the U.S. DCD trial," 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 use of OCS is actively expanding the donor pool, as I expected. It is time we stop considering heart transplant as a severely supply limited resource. With OCS we will be able to expand access to this life saving therapy to more end-stage heart failure patients."

"This first-of-its kind DCD heart approval represents a transformative milestone for the U.S. heart transplant community as it stands to meaningfully expand the pool of eligible donor hearts while also enhancing our customer's ability to utilize our OCS technology," said Waleed Hassanein, MD, President and Chief Executive Officer. "The approval also marks the achievement of our final near-term regulatory milestone. We are now focused on leveraging our unique position to drive meaningful commercial traction and cement our global leadership position to transform transplant therapy for decades to come."

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 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 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; 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 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; 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, 2021, 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.

Investor Contact:
Brian Johnston
332-895-3222

Investors@transmedics.com

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