



TransMedics Announces Presentation of OCS Liver PROTECT Trial Results and is Recognized as Winner of The People's Choice Award for Most Impactful Presentation at the American Transplant Congress (ATC 2021)

June 8, 2021

ANDOVER, Mass., June 8, 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, announced that the complete results of the OCS™ Liver PROTECT Trial ("PROTECT") were presented virtually at the American Transplant Congress on Tuesday June 8th, 2021. The presentation won the People's Choice Award for the most impactful presentation at the ATC 2021.

Dr. James F. Markmann, Chief of the Division of Transplantation Surgery at Massachusetts General Hospital and the lead investigator of the PROTECT trial, presented the results, which included 12-month follow up data and were also highlighted in an abstract entitled *Superior Post-transplant Clinical Outcomes Using Portable Normothermic Perfusion and Assessment with the Organ Care System (OCS) Liver System: 1-year Outcomes of the OCS Liver Protect Randomized Controlled Trial*. The OCS Liver system premarket approval (PMA) application is currently under review by FDA and an Advisory Panel Meeting is expected to review the PROTECT results in the near future.

At ATC 2021, Dr. Markmann reported that PROTECT met its primary effectiveness endpoint and demonstrated a significant reduction in early allograft dysfunction (EAD) with OCS (OCS 18% vs. Control 31%, $p=0.009$). OCS preserved livers also demonstrated a significant reduction in histopathological evidence of IR injury after reperfusion and significant attenuation of reperfusion syndrome in the recipient. OCS use was also associated with significant reduction of ischemic biliary complications at one year, a leading cause of graft failure after liver transplant (OCS 2.6% vs. Control 9.9%, $p=0.019$). The OCS Liver System enabled ex-vivo liver allograft assessment and resulted in significantly higher utilization of livers from donors after cardiac death (DCD) (OCS 51% vs. Control 25%, $p=0.007$). PROTECT's safety endpoint was met with low mean liver graft related serious adverse events (OCS 0.046 to Control 0.075, non-inferiority $p<0.0001$). Patient survival at one year was high at 94% for both OCS and Control arms.

"The PROTECT trial results demonstrated superior short and mid-term clinical outcomes and improved utilization of donor livers for transplantation," said Dr. Markmann. "The advent of a portable extracorporeal donor liver machine perfusion offers a convenient and effective approach to both assess and enhance donor liver function, thereby improving transplant safety, expanding the liver donor pool, and reducing waitlist mortality."

"We would like to congratulate Dr. Markmann and all of the PROTECT trial investigators on these superior and potentially transformative results in liver transplantation," said Waleed Hassanein, MD, President and Chief Executive Officer. "We are looking forward to our upcoming FDA Advisory Panel meeting to discuss the potential approval of the OCS Liver System based on these PROTECT trial results."

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 Liver 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

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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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