



TransMedics Announces Positive FDA Advisory Committee Vote for the OCS Liver System

Jul 14, 2021 at 9:00 PM EDT

Panel votes unanimously in support of the OCS Liver System's safety and effectiveness

ANDOVER, Mass., July 14, 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 today that after review and discussion of TransMedics' clinical evidence from the OCS Liver PROTECT trial, the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee convened by the U.S. Food and Drug Administration ("FDA") has issued a favorable vote in support of approval of the OCS Liver System.

The panel voted 14 to 0, that there is reasonable assurance that the OCS Liver System is effective and 14 to 0, that there is reasonable assurance of the OCS Liver System's safety. The panel voted 12 to 1, with 1 abstaining, that the benefits of the OCS Liver System outweigh its risks.

"This vote marks a key milestone as we move towards potential FDA approval of the OCS Liver technology, which stands to benefit U.S. patients with end-stage liver failure. We are looking forward to working collaboratively with the FDA to finalize the review of the OCS Liver PMA," said Dr. Waleed Hassanein, President and Chief Executive Officer. "I want to take this opportunity to thank the OCS Liver PROTECT Trial investigators, trial coordinators, patients who enrolled in the OCS Liver PROTECT Trial, and the TransMedics Liver team."

"The OCS Liver PROTECT Trial demonstrated that the OCS Liver has the ability to provide superior clinical outcomes and improve utilization of donor livers for transplantation. This is truly a game-changer in the field of liver transplantation," said Dr. James F. Markmann, Chief of the Division of Transplantation Surgery at Massachusetts General Hospital and the lead investigator of the OCS Liver PROTECT Trial. "The OCS Liver System allows surgeons to both assess and enhance donor liver function before transplantation, which can improve transplant safety and enables the use of donor livers that would otherwise go unused. If approved by the FDA, I believe the OCS Liver will allow us to provide more life-saving transplants for patients with end-stage liver disease."

"Today's FDA panel vote brings us closer to potentially having all three OCS products FDA approved and commercially available in the U.S. for lung, heart and liver transplantation," Dr. Waleed Hassanein concluded.

FDA Advisory Committees provide the FDA with independent opinions and nonbinding 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 ("PMA") for the use of the OCS Liver System for transplantation after completion of its review of the PMA.

The OCS Lung System is approved in the U.S., and the OCS Heart System is currently under review by the FDA after receiving a positive vote by the FDA's Circulatory System Device Advisory Panel in April.

PROTECT Trial

The OCS Liver PROTECT trial 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 in the incidence of ischemic biliary complications through 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, which resulted in a 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 a low average number of 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.

About the OCS System

The OCS System is the only portable, multi-organ platform for donor lungs, hearts and livers for transplantation. The OCS System mimics the human body by providing donor organs with warm, oxygenated blood perfusion throughout preservation that maintains the organs in a living, functional state. The assessment capabilities of the OCS System enable diagnostic evaluation to allow for the analysis of organ function and viability prior to transplant. Normothermic perfusion on the OCS System optimizes the organ conditions and allows for therapeutic intervention through replenishing oxygen and nutrients.

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 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, 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.

 View original content to download multimedia:<https://www.prnewswire.com/news-releases/transmedics-announces-positive-fda-advisory-committee-vote-for-the-ocs-liver-system-301334292.html>

SOURCE TransMedics Group, Inc.

Investor Contact: Brian Johnston, 631-807-1986, Investors@transmedics.com