TransMedics Announces Publication of OCS™ Liver PROTECT Trial Results in JAMA Surgery

Jan 5, 2022 at 6:41 PM EST

ANDOVER, Mass., Jan. 5, 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 the publication of OCS™ Liver PROTECT Trial Results in *JAMA Surgery*, a member of the Journal of the American Medical Association (JAMA) Network. The publication, titled *Impact of Portable Normothermic Blood-Based Machine Perfusion on Outcomes of Liver Transplant*, was published online on January 5, 2022. The OCS™ Liver System was approved by the U.S. Food and Drug Administration (FDA) for the preservation and assessment of donor livers for transplant from donors after brain death (DBD) and after circulatory death (DCD) on September 29, 2021.

"The PROTECT trial showed superior short-term and mid-term clinical outcomes and higher numbers of donor livers used for transplant," said Dr. James F. Markmann, Chief of the Division of Transplantation Surgery at Massachusetts General Hospital and the lead author of the manuscript. "We concluded, that the advent of portable, extracorporeal, donor liver machine perfusion offers for the first time a convenient and effective approach to both clinically assess and enhance donor liver function, thereby improving transplant safety, expanding the liver donor pool, and reducing waiting list mortality – This is a game changer in liver transplantation."

"We believe these superior clinical results represent a groundbreaking milestone for liver transplantation," said Waleed Hassanein, MD, President and Chief Executive Officer. "This publication is further evidence that the OCS Liver System along with our OCS Lung and OCS Heart Systems will significantly improve patient outcomes and expand the pool of eligible donors, thereby saving more lives."

About the OCS™ Liver PROTECT Trial

The OCS™ Liver PROTECT Trial was a two-armed, multicenter, prospective, randomized, controlled pivotal trial to evaluate the effectiveness and safety of the OCS™ Liver to preserve and assess donor livers intended for transplantation. The trial enrolled 300 patients, with 153 patients randomized to transplantation using the OCS™ Liver and 147 patients randomized to the control group, which used cold storage methods. Enrollment was completed in October 2019 with transplants conducted across a network of 20 major liver transplant centers in the U.S.

The primary effectiveness endpoint for the study was the incidence of EAD in the first 7 days following transplant procedures. The primary safety endpoint for the study was the average number of liver graft related serious adverse events (SAEs) per patient measured over 30 days following transplant procedures. The study also measured the rate of DCD & DBD donor utilization, the incidence of ischemic biliary cholangiopathy, and other clinical endpoints throughout the first year after liver transplantation.

The study results demonstrated that the primary effectiveness end point was met by a significant decrease in EAD (27 of 150 [18%] vs 44 of 141 [31%]; P = .01) and that the OCS™ Liver preserved livers had significant reduction in histopathologic evidence of ischemia-reperfusion injury after reperfusion (eg, less moderate to severe lobular inflammation: 9 of 150 [6%] for OCS™ Liver vs 18 of 141 [13%] for ischemic cold storage (ICS); P = .004). The OCS™ Liver resulted in significantly higher use of livers from donors after cardiac death (28 of 55 [51%] for the OCS™ Liver vs 13 of 51 [26%] for ICS; P = .007). The OCS™ Liver was also associated with significant reduction in incidence of IBC 6 months (1.3% vs 8.5%; P = .02) and 12 months (2.6% vs 9.9%; P = .02) after transplant.

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 of the OCS Liver. 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 developments in the United States, European 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 additional 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.

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

View original content to download multimedia:https://www.prnewswire.com/news-releases/transmedics-announces-publication-of-ocs-liver-protect-trial-results-in-jama-surgery-301455110.html

SOURCE TransMedics Group, Inc.