TransMedics Announces Positive Top-line Results from U.S. Pivotal OCS™ Liver PROTECT Trial

May 26, 2020 at 7:09 AM EDT

Primary Effectiveness and Safety Endpoints Were Met. The OCS Liver Achieved Statistical Superiority of The Primary Effectiveness Endpoint by Demonstrating Significant Reduction of Early Allograft Dysfunction (EAD) Compared to Control.

ANDOVER, Mass., May 26, 2020 (GLOBE NEWSWIRE) -- 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 reported positive top-line results from its U.S. Pivotal OCS Liver PROTECT Trial. The trial achieved its primary clinical objectives by meeting both the primary and secondary effectiveness and safety endpoints. For the primary effectiveness endpoint, the use of OCS Liver resulted in a significantly lower incidence of early allograft dysfunction (EAD) compared to control (17.3% OCS vs. 30.5% Control p=0.009) across both the donors after brain death (DBD) and donors after circulatory death (DCD) cohorts in the trial. EAD is the most common severe complication that occurs early after liver transplantation. EAD serves as a potential indicator of preservation injury to the donor liver and is associated with significant increase in ICU and hospital stay. The trial also met its three secondary effectiveness endpoints. The OCS Liver was able to maintain a near physiologic functioning state and monitor the condition of the liver outside of the human body; patient survival at 30-days post-transplant was high and non-inferior to control (99.3% OCS vs. 99.3% Control p=0.0004). In addition, the use of OCS Liver resulted in a significantly lower incidence of ischemic cholangiopathy complications at 6 months post-transplantation (1.4% OCS vs. 8.5% Control p=0.005), a leading cause of late graft failure after liver transplantation. The primary safety endpoint was also met, as the average liver graft-related serious adverse events (SAEs) per patient observed using the OCS Liver was non-inferior to Control (0.046 OCS vs. 0.075 Control p<0.0001). In the OCS Liver PROTECT Trial, 155 donor livers, including both DBD and DCD, were instrumented on the OCS Liver, of which 152 were successfully transplanted, yielding a 98.1% utilization rate.

"Results from the OCS Liver PROTECT Trial set the stage for transformative changes in the field of liver transplantation by validating the benefits of reducing ischemic injury on the donor liver while continuously optimizing perfusion and assessing liver function on the OCS System," said Dr. James Markmann, MD PhD, Chief Division of Transplant Surgery at Massachusetts General Hospital and the lead investigator of the OCS Liver PROTECT Trial. "We are looking forward to submitting these provocative clinical results for publication in a premier peer reviewed journal soon."

"To our knowledge, these results from the OCS Liver PROTECT trial represent the first time a new technology or therapy has had a positive impact on both EAD and ischemic cholangiopathy in liver transplantation," said Dr. Malcolm MacConmara, MD, Director of the Organ Research Lab at UT Southwestern Medical Center and a co-investigator of the OCS Liver PROTECT Trial. "If approved, this would safely expand the utilization of donor livers and significantly increase the number of livers available for life-saving transplantation."

"In addition to improved graft outcomes achieved with the OCS Liver System, we have seen in our clinical experience during the trial significant improvement in safety in the conduct of liver transplantation with adverse intraoperative reperfusion events being virtually eliminated after the use of the OCS Liver System," said Dr. Marwan Abouljoud, MD, Director of the Henry Ford Transplant Institute and a co-investigator of the OCS Liver PROTECT Trial. "I believe this will open the gateway to using more livers for transplantation safely."

"We are humbled and excited by these compelling top-line results from our OCS Liver PROTECT Trial," said Waleed Hassanein, MD, President and Chief Executive Officer. "Data from the trial further support our belief that the OCS Liver System along with our OCS Lung and OCS Heart Systems has the potential to meaningfully improve patient outcomes and increase the number of organ transplants to help end-stage organ failure patients. We are grateful for all the trial investigators, their teams and institutions for completing this seminal trial in liver transplantation."

About OCS Liver PROTECT Trial:

The OCS™ Liver PROTECT Trial is 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 18 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.

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. Investors are cautioned not to place undue reliance on these forward-looking statements, including statements about our results of operations, commercial opportunity and the rate of adoption and benefits of the OCS. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement. Applicable risks and uncertainties include those related to the potential utilization of the OCS Liver for liver transplantations; our anticipation 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; 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 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 28, 2019 and in our quarterly report on Form 10-Q for the quarter ended March 31, 2020, which are available on the SEC’s website at www.sec.gov. 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 (except as otherwise noted) 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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Source: TransMedics