



TransMedics to Provide Update on Ongoing Clinical Programs at the International Society of Heart and Lung Transplantation 2026 Annual Meeting

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Unveils New Controlled Hypothermic Organ Preservation System (CHOPS) to Expand its Product Portfolio and to Facilitate Enrollment in Control Arms of OCS ENHANCE Heart Part B and OCS DENOVO Lung Clinical Trials

ANDOVER, Mass., April 23, 2026 /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, is today providing an update on its ongoing clinical programs at the International Society of Heart and Lung Transplantation (ISHLT) 2026 Annual Meeting in Toronto, Canada. At the meeting, TransMedics will unveil its new controlled, active cooling preservation device, the Controlled Hypothermic Organ Preservation System (CHOPS), aimed at facilitating the enrollment of the control arms of the OCS ENHANCE Heart Part B and OCS DENOVO Lung clinical trials.

CHOPS is a true active cooling device that provides a consistent and stable controlled cold storage environment for donor organs at a variety of temperature ranges that are established based on the recipient transplant program's preferences. In comparison, other current cold storage techniques use phase changing material that makes it difficult to control or adjust temperatures. CHOPS will be regulated by the U.S. Food and Drug Administration (FDA) as a new, stand-alone device for controlled hypothermic preservation. Importantly, TransMedics will submit an Investigation Device Exemption (IDE) amendment to allow CHOPS to serve as the control arm for both Part B of ENHANCE Heart and DENOVO Lung Trials.

The FDA granted full approval of TransMedics' IDE for the Next-Generation OCS ENHANCE Heart trial in February 2026 and of the company's IDE for its Next-Generation OCS DENOVO Lung trial in January 2026. Part B of the ENHANCE trial is designed to assess the superiority of OCS Heart perfusion in donation after brain death (DBD) cases when compared to DBD cases using static cold storage methods. The OCS DENOVO trial is designed to assess the superiority of OCS Lung perfusion in DBD and donation after circulatory death (DCD) cases when compared to cases using static cold storage methods.

"Our commitment to building the highest level of prospective clinical evidence is what is driving us to conduct these two major clinical programs for heart and lung transplantation," said Waleed Hassanein, M.D., President and Chief Executive Officer. "With FDA review expected to conclude in the coming months, we anticipate being well positioned to support rigorous, FDA-acceptable comparisons in both the ENHANCE Heart Part B and DENOVO Lung trials. Importantly, if approved, this approach would also expand TransMedics' product offerings to include true controlled active cooling preservation devices to serve a broader segment of heart and lung transplant patients globally, based on prospective level 1 evidence."

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. These forward-looking statements address various matters, including, among other things, future results and events, including the potential safety, efficacy, regulatory review or approval and commercial success of TransMedics' products and product candidates and those relating to the company's product development, pre-clinical testing, clinical studies, clinical and regulatory milestones and timelines, plans for TransMedics' Controlled Hypothermic Organ Preservation System, the company's IDE amendment submission, comparability in TransMedics' ENHANCE Heart Part B and DENOVO Lung trials, and the potential expansion of TransMedics' product offerings. For this purpose, all statements other than statements of historical facts are forward-looking statements. The words "believe," "may," "will," "estimate," "continue," "anticipate," "intend," "expect," "should," "could," "target," "predict," "seek" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are subject to a number of risks and uncertainties. Our management cannot predict all risks, nor can we assess the impact of all factors 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 and uncertainties, 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 in or implied by the forward-looking statements. Some of the key factors that could cause actual results to differ include: the fluctuation of our financial results from quarter to quarter; our ability to attract, train and retain key personnel; our dependence on the success of the Organ Care System ("OCS"); our ability to expand access to the OCS through our National OCS Program ("NOP"); our ability to improve the OCS platform, including by developing the next generation of the OCS products or expanding into new indications, and the development, and potential commercialization of our OCS Kidney device and CHOPS; the timing or results of clinical trials for the OCS, including pre- and post-approval studies; our ability to sustain profitability; our need to raise additional funding and our ability to obtain it on favorable terms, or at all; our ability to use net operating losses and research and development credit carryforwards; that we have identified a material weakness in our internal control over financial reporting, and that we may identify additional material weaknesses in the future; our ability to scale our manufacturing and sterilization capabilities to meet increasing demand for our products; the rate and degree of market acceptance of the OCS; our ability to educate patients, surgeons, transplant centers and private and public payors on the benefits offered by the OCS; our dependence on a limited number of customers for a significant portion of our revenue; our ability to obtain or maintain

regulatory approvals or clearances for our OCS products in the United States, the European Union, and other select jurisdictions worldwide as well as other product candidates, including CHOPS; our ability to adequately respond to the Food and Drug Administration ("FDA"), or other competent authorities, follow-up inquiries in a timely manner; the impact of healthcare policy changes, including recently enacted or potential future legislation or administrative actions affecting or reforming the U.S. healthcare system, Organ Procurement and Transplantation Network ("OPTN"), or the FDA; the performance of our third-party suppliers and manufacturers; our use of third parties to transport donor organs and medical personnel for our NOP and our ability to maintain and grow our transplant logistics capabilities to support our NOP to reduce dependence on third party transportation, including by means of attracting, training and retaining pilots, and the acquisition, maintenance or replacement of fixed-wing aircraft for our aviation transportation services or other acquisitions, joint ventures or strategic investments; our ability to maintain Federal Aviation Administration or other regulatory licenses or approvals for our aircraft transportation services; price increases of the components of our products and maintenance, parts and fuel for our aircraft; 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 protect, defend, maintain and enforce our intellectual property rights relating to the OCS and avoid allegations that our products or services 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 impact of a shutdown of the U.S. government; the extent and success of competing products or procedures that are or may become available; our ability to service our 1.50% convertible senior notes, due 2028; our existing and any future indebtedness, including our ability to comply with affirmative and negative covenants under our credit agreements to which we will remain subject until maturity; the impact of any product recalls or improper use of our products; our international expansion plans and the costs related thereto; our estimates regarding revenue, expenses and needs for additional financing; and other factors that may be described in our filings with the Securities and Exchange Commission (the "SEC"). Additional information will be made available in our annual and quarterly reports and other filings that we make with the SEC. The forward-looking statements in this press release 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 we are not able 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

Hannah Jeffrey

Investors@transmedics.com

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