TransMedics Receives FDA IDE Approval to Initiate Next-Generation OCS Heart Trial

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ANDOVER, Mass., Aug. 4, 2025 /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 that the U.S. Food and Drug Administration (FDA) has granted conditional approval of its Investigational Device Exemption (IDE), allowing the company to proceed with the initiation of its Next-Generation OCS ENHANCE Heart trial.

The ENHANCE trial is a two-part clinical trial. Part A is designed to support prolonged heart perfusion using OCS™ Heart System. Part B is intended to demonstrate the superiority of OCS Heart perfusion in donation after brain death (DBD) cases when compared to DBD cases using static cold storage methods. Part B is intended to support the potential expansion of OCS Heart clinical indications to include DBD hearts that are not currently eligible for OCS perfusion and preservation. The trial's total sample size, across both Part A and Part B, is expected to exceed 650 patients. TransMedics believes this would constitute the largest heart preservation for transplant trial ever, worldwide. Details of the OCS ENHANCE Heart trial will be made available on clinicaltrials.gov.

"The recent FDA approvals to initiate our Next-Gen OCS ENHANCE Heart and DENOVO Lung trials mark key milestones in our ongoing commitment to transforming the standard of care and address the major clinical needs of the cardiothoracic transplant community," said Waleed Hassanein, MD, President and Chief Executive Officer. "We are thrilled to be in a position to initiate both trials in the fourth quarter of 2025 while we continue to work collaboratively with the FDA to address any remaining questions related to pre-clinical testing. As I have stated before, we hope these two trials will be major catalysts for clinical adoption for both heart and lung throughout 2026 and beyond."

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 our products and product candidates and those relating to the Company's product development, pre-clinical testing, clinical studies, clinical and regulatory milestones and timelines, commercial opportunity and timelines, business strategies, potential growth opportunities and other statements that are predictive in nature. 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," "hope," "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 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; 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 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; 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 of benefits offered by the OCS; our dependence on a limited number of customers for a significant portion of our revenue; our ability to maintain regulatory approvals or clearances for our OCS products in the United States, the European Union, and other select jurisdictions worldwide; our ability to adequately respond to 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 reforming the U.S. healthcare system 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 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 ("FAA") 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; the timing or results of post-approval studies and 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 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 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; the impact of any product recalls or improper use of our products; our estimates regarding revenues, 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.

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