



TransMedics Announces Temporary Postponement of OCS Heart FDA Advisory Panel Committee Meeting

September 28, 2020

ANDOVER, Mass., Sept. 28, 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 announced that the FDA has temporarily postponed the Advisory Committee meeting to review TransMedics' premarket approval application for its OCS Heart. The postponement of the meeting, which was previously scheduled for October 7th, 2020 will allow the FDA time to review additional, already collected, short and longer-term data from the OCS Heart EXPAND trial and EXPAND Continued Access Protocol. The FDA's Office of Health Technology 2 (Cardiovascular Devices) has communicated to TransMedics that it will review the additional data expeditiously to allow rescheduling of the Advisory Panel meeting to occur in the near future.

"While we are very disappointed by this unforeseen delay, this development demonstrates the collaborative work TransMedics and FDA are doing together to ensure that FDA regulatory decisions related to the OCS Heart are made with the most informative and complete scientific data. We remain highly confident that the results of the OCS Heart EXPAND trial and the associated EXPAND Continued Access Protocol support FDA approval of the OCS Heart to help patients in need of heart transplant in the U.S.," said Waleed Hassanein, M.D., President and Chief Executive Officer.

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, the anticipated timing of the Advisory Committee meeting to review TransMedics' premarket approval application for its OCS Heart and likelihood of regulatory approval. 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: 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 or results of clinical trials for the OCS; regulatory developments in the United States, European Union and other jurisdictions; 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 reports on Form 10-Q for the quarters ended March 31, 2020 and June 30, 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 presentation. 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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