



TransMedics Announces Scheduling of OCS Heart FDA Advisory Committee Meeting

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ANDOVER, Mass., March 1, 2021 /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 FDA's Office of Health Technology 2 (Cardiovascular Devices) has communicated its intent to hold a Circulatory Systems Device Advisory Panel meeting on April 6, 2021 to review TransMedics' premarket approval application for the OCS Heart System.



"We are looking forward to this important milestone and to hopefully achieving a positive conclusion of the FDA's review process of our OCS Heart PMA application," 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, June 30, 2020, & September 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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Investor Contact: Brian Johnston, 631-807-1986, Investors@transmedics.com