TransMedics Announces Scheduling of OCS Liver FDA Advisory Committee Meeting

June 10, 2021

ANDOVER, Mass., June 10, 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 U.S. Food and Drug Administration ("FDA") has announced the scheduling of a public advisory committee meeting during which it will review information regarding TransMedics' premarket approval application for the OCS Liver System. The Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee will meet on July 14, 2021 to discuss, make recommendations, and vote on a recommendation for approval of the OCS Liver System.

"We are looking forward to presenting the OCS Liver PROTECT data to the advisory committee panel in support of our PMA for the OCS Liver System. This is another important milestone to bring TransMedics closer to having all of our three organ platforms approved by FDA in 2021," said Waleed Hassanein, M.D., President and Chief Executive Officer.

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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 Liver 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" in our Annual Report on Form 10-K for the year ended December 31, 2020, which is 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 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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