

Organovo Announces Appointment of Steven G. Hughes, M.D. as Chief Medical Officer

August 1, 2018

SAN DIEGO, Aug. 01, 2018 (GLOBE NEWSWIRE) -- Organovo Holdings, Inc. (NASDAQ:ONVO) ("Organovo") today announced that Steven G. Hughes has been named Chief Medical Officer. Dr. Hughes is an industry veteran who brings significant experience directing clinical development and medical affairs teams at leading biopharma companies.

Dr. Hughes most recently served as the Chief Clinical Development Officer at Ionis Pharmaceuticals, where he led a team that managed the global clinical development of 25 drugs across 10 therapeutic areas including cardiovascular, metabolic, oncology and rare diseases. Previously, he held positions as Global Medical Lead, Oncology Clinical Development and Medical Director, UK & Ireland at Biogen Idec. Dr. Hughes also held numerous senior clinical development, medical affairs and leadership positions of increasing responsibility at CSL Behring and Sanofi. Dr. Hughes is board certified in Pharmaceutical Medicine and received his medical degree from Imperial College, London. He also has an MBA with distinction from Imperial College Business School.

"Dr. Hughes brings an extensive and successful track record of progressing cutting edge therapeutic opportunities from the preclinical stage through to commercialization," said Taylor J. Crouch, CEO, Organovo. "His outstanding background establishing the teams, processes, external expert support and patient group advocacy in orphan diseases will be critical as we advance our multiple Investigational New Drug ("IND")-track liver therapeutic tissue program in a range of medical applications aimed at addressing serious unmet needs. As we move through fiscal 2019, his experience will be invaluable as we pursue orphan drug designation for a second rare disease indication and commence IND-enabling studies for treating Alpha-1-antitrypsin deficiency. With Dr. Hughes' guidance, our objective is to end this fiscal year with two liver therapeutic tissue programs on track for an IND targeted for calendar 2020."

"I'm thrilled to join Organovo and look forward to being part of a team that has the potential to transform the lives of people that are fighting these rare and very serious diseases," said Steven G. Hughes, chief medical officer, Organovo. "I've been privileged in my career to help design and steer productive drug pipelines, shepherding many important products through complex scientific and regulatory pathways. Organovo has a broad range of promising opportunities in the years ahead, and I can't wait to dive in and get started."

About Organovo Holdings, Inc.

Organovo is a biotech platform company that has developed a leadership position with its revolutionary ability to 3D bioprint tissues with human functionality. The Company is pursuing multiple IND-track programs to develop its NovoTissues® to address a number of serious unmet medical needs in adult and pediatric populations, initially focusing on liver disease. Organovo's first IND-track program for Alpha-1-antitrypsin deficiency recently received orphan drug designation from the FDA, and the Company expects to file its first IND in 2020. In order to help fund its plan to initiate multiple IND-track programs, the Company is providing access to its ExViveTMin vitro tissue disease modeling platform to facilitate high value drug discovery and development collaborations. Organovo's wholly-owned subsidiary, Samsara Sciences, provides the Company and its clients with high quality human liver and kidney cells for research applications. Organovo is changing the shape of life science research and transforming medical care. Learn more at www.organovo.com.

Forward-Looking Statements

Any statements contained in this press release that do not describe historical facts constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. Any forward-looking statements contained herein are based on current expectations, but are subject to a number of risks and uncertainties. Forward-looking statements include, but are not limited to, statements regarding the potential benefits and therapeutic uses of the Company's therapeutic liver tissue, including the benefits of an orphan designation; the Company's expectations regarding the FDA regulatory pathway and anticipated timelines for its regulatory filings; the potential market opportunity for the Company's therapeutic tissue candidates; and customer demand for and acceptance of our disease modeling and other in vitro tissue platforms. The factors that could cause the Company's actual future results to differ materially from current expectations include, but are not limited to, risks and uncertainties relating to the possibility that the final results of the Company's preclinical studies may be different from the Company's studies or interim preclinical data results and may not support further clinical development of its therapeutic tissues; the Company may not successfully complete the required preclinical and clinical trials required to obtain regulatory approval for its therapeutic tissues on a timely basis or at all; risks that competitive products may adversely impact the market opportunity for the Company's therapeutic tissue candidates; the Company's ability to develop, market and sell products and services based on its technology; the expected benefits and efficacy of the Company's products, services and technology; the Company's ability to execute framework agreements involving multi-year commitments and routine use on a timely basis, or at all; the Company's ability to successfully complete studies and provide the technical information required to support market acceptance of its products, services and technology, on a timely basis or at all; the Company's business, research, product development, regulatory approval, marketing and distribution plans and strategies, including its use of third party distributors; the Company's ability to recognize deferred revenue; and the Company's ability to meet its fiscal-year 2019 goals and outlook. These and other factors are identified and described in more detail in the Company's filings with the SEC, including its Annual Report on Form 10-K filed with the SEC on May 31, 2018. You should not place undue reliance on these forward-looking statements, which speak only as of the date that they were made. These cautionary statements should be considered with any written or oral forward-looking statements that the Company may issue in the future. Except as required by applicable law, including the securities laws of the United States, the Company does not intend to update any of the forward-looking statements to conform these statements to reflect actual results, later events or circumstances or to reflect the occurrence of unanticipated events.

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Organovo, Inc.