



## Organovo Partners With IIAM on Multi-Year Clinical Biomaterial Sourcing Agreement

November 12, 2018



SAN DIEGO, Nov. 12, 2018 (GLOBE NEWSWIRE) -- Organovo Holdings, Inc. (NASDAQ:ONVO) ("Organovo"), a biotechnology company pioneering the development of 3D bioprinted tissues aimed at treating a range of serious adult and pediatric liver diseases, today announced that it has entered into a cell and tissue clinical sourcing agreement with the International Institute for the Advancement of Medicine ("IIAM"). Under the terms of the agreement, IIAM will provide Organovo with donated organs that have not been utilized for transplantation with high potential benefit for generating the cell-based building blocks for Organovo's therapeutic liver tissue development program.

"We continue to lay the groundwork for the potential start of human clinical trials in calendar 2020, as we develop our NovoTissues<sup>®</sup> to address liver disease in adult and pediatric populations," said Taylor J. Crouch, CEO, Organovo. "IIAM is one of the world's largest providers of organs and tissues designated for medical research and development. We're thrilled to more closely align our groundbreaking work with IIAM. This partnership, along with our own expertise in isolating, characterizing and utilizing specialized human liver cells, will enable us to create implantable 3D bioprinted liver tissue patches destined for patient treatment. Our clinical program expects to serve patient populations that are in desperate need of new treatment options. Where possible, we will also leverage the distribution capabilities of our Samsara subsidiary to put these valuable cells and tissues into the hands of other leading liver researchers."

Crouch continued, "As we head into calendar 2019, we're on track to pursue orphan designation for a second rare disease indication and to commence Investigational New Drug ("IND") enabling studies for treating end stage liver diseases including Alpha-1-antitrypsin deficiency, ultimately culminating in a targeted IND filing for calendar 2020."

"IIAM is excited to collaborate with Organovo and Samsara as they work toward clinical applications of liver cells as a therapy for the patient populations affected with inborn metabolic errors," said Gina Dunne Smith, executive director, IIAM. "This is yet another way for donors and their families to save or improve the lives of others. As we move forward, these are cutting edge research projects that are exciting for our entire team."

"MTF Biologics could not be more pleased with our new agreement to support Organovo and their therapeutic endeavors," said Joe Yaccarino, president and CEO, MTF Biologics. "As the parent company to IIAM, we are pushing to increase opportunities for biologics and clinical modalities of many tissue forms. This latest collaboration is directly in line with our mission of saving and healing lives through honoring donated gifts, serving patients and advancing science."

### **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<sup>®</sup> 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 support its plan to initiate multiple IND-track programs, the Company is providing access to its ExVive<sup>TM</sup> *in 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](http://www.organovo.com).

### **About IIAM**

THE INTERNATIONAL INSTITUTE FOR THE ADVANCEMENT OF MEDICINE (IIAM) is at the forefront of providing non-transplantable organs to the medical research community for purposes of combatting and curing disease. IIAM has unprecedented collaborations in the U.S. to source livers and other organs for therapeutic applications and pre-clinical investigations targeting a range of debilitating metabolic disorders. As a nonprofit with more than 30 years of experience in the field, IIAM is a known and trusted partner to both organ procurement organizations and research institutions worldwide. IIAM works closely with them to honor donor and donor family intentions to the fullest by anticipating the next frontier of research requiring human tissue. IIAM leads the way in educating the next generation of researchers so that every donor's legacy leaves the world a healthier place. IIAM is a wholly-owned subsidiary of MTF Biologics, also known as Musculoskeletal Transplant Foundation, a non-profit organization based in Edison, NJ and the world's largest tissue bank, whose mission is to save and heal lives by honoring donated gifts, serving patients and advancing science.

### **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 its 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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