



## Organovo to Present New Preclinical Data on 3D Bioprinted Human Liver Tissues for the Treatment of Tyrosinemia I at the Liver Meeting® 2018 (AASLD)

October 15, 2018

SAN DIEGO, Oct. 15, 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 it will present data on the performance of its liver therapeutic tissue in an animal model of hereditary tyrosinemia Type 1 ("HT-1") at the Liver Meeting 2018® (American Association for the Study of Liver Diseases or "AASLD") being held November 9-13, 2018 in San Francisco. The Company will also have a poster presentation comparing the performance characteristics of liver cells in an *in vitro* setting between non-diseased and non-alcoholic fatty liver disease ("NAFLD") donors. The abstracts are available in the [Online Planner](#) on the AASLD website.

Organovo implanted its 3D bioprinted human liver tissue patches onto the livers of FRG knockout mice, and is presenting data from promising early studies in this established model for HT-1, an inborn error of metabolism ("IEM") characterized by severe liver damage due to increased tyrosine levels. The liver tissue patches are composed of human hepatocytes and select non-parenchymal cells. Serum and histopathologic evaluation of the implanted therapeutic tissue showed engraftment, retention and functionality through at least 35 days post-implantation, while also demonstrating the sustained presence of key human liver proteins such as albumin in the animal bloodstream. Importantly, treated animals showed an improvement in the median survival rate versus non-treated control animals.

"We're encouraged that our 3D bioprinted liver tissues continue to show retention and functionality in a range of animal disease models, including Alpha-1-antitrypsin deficiency and HT-1, where there is critical unmet need and a potentially significant impact on patient outcomes because of the dire shortage of liver transplants," said Taylor J. Crouch, CEO, Organovo. "In each case, our objective in implanting a healthy tissue patch is to restore function or offset the deficiency of a specific enzyme abnormality, with the ultimate goal of delaying or reducing the need for a transplant. We remain on track for our first IND submission in calendar 2020."

Referring to the poster presentation, Dr. Sharon Presnell, chief scientific officer, Organovo, commented, "As we continue to build our library of healthy and diseased liver tissues and isolated primary cells, we are uncovering key functional and genetic features of cells that correlate with specific donor and disease-state attributes. The data to be presented at AASLD highlights Samsara's leadership in the isolation and specialized characterization of NAFLD/NASH-origin primary human liver cells, contributing to a better understanding of liver disease and its potential treatments."

The Company's poster(s) and oral presentation are as follows:

**Title:** **The Performance Characteristics of Isolated Human Liver Cells Correlate with Donor Attributes in a Cohort of Tissues from Non-Diseased and NAFLD Donors**

**Date:** Saturday, November 10, 2018, 2:00 pm PT – Moscone Center North/South Building, Hall C

**Publication:** 1305

**Title:** **Long-Term Performance of Implanted Bioprinted Human Liver Tissue in a Mouse Model of Tyrosinemia I (Oral Presentation)**

**Date:** Sunday, November 11, 2018, 11:30 am PT – Moscone Center North/South Building, Room 214/216

**Publication:** 0083

### **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 support its plan to initiate multiple IND-track programs, the Company is providing access to its ExVive™ *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).

### **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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