



Organovo Presents New Preclinical Data on 3D Bioprinted Human Liver Tissues for the Treatment of Inborn Errors of Metabolism at The Liver Meeting® 2017 (AASLD)

October 20, 2017

SAN DIEGO, Oct. 20, 2017 (GLOBE NEWSWIRE) -- Organovo Holdings, Inc. (NASDAQ:ONVO) ("Organovo") today presented new preclinical data showing extended survival and sustained functionality of its 3D bioprinted human liver tissue when implanted into diseased animal models. This data will be presented at The Liver Meeting 2017 (American Association For The Study of Liver Diseases or "AASLD") by Vaidehi Joshi, Scientist I, Therapeutics, at Organovo.

Organovo previously implanted its 3D bioprinted human liver tissue patches onto the livers of healthy NOD/SCID mice, and is now presenting additional data from promising early studies in an established model for alpha-one-antitrypsin deficiency ("A1AT"). The tissue was composed of human hepatocytes and select non-parenchymal cells. Serum and histopathologic evaluation of the implanted therapeutic tissue showed engraftment, retention and a high degree of disease clearing through 125 days post-implantation, a significant increase in duration from the Company's first preclinical studies, which demonstrated functionality through 28 days. These results demonstrate a significant increase in the reported duration of implanted human hepatocyte synthetic function, demonstrating sustained presence of key human liver proteins such as albumin and A1AT in the animal bloodstream. Importantly, pathologic evaluation of diseased animals receiving implanted bioprinted liver tissues suggests an approximately 75 percent reduction in the pathologic hallmarks of the disease in treated animals versus non-treated control animals in the region of implant.

"With tens of thousands of patients being treated for inborn errors of metabolism ("IEMs") in the U.S., and an annual cost per patient that exceeds \$250,000 for drug therapy alone, Organovo continues to advance a novel therapeutic solution for direct surgical implantation," said Eric David, M.D., J.D., chief strategy officer and executive vice president of preclinical development, Organovo. "Our preclinical data continues to show robust engraftment and durability of the liver tissue and strong early evidence of successfully impacting the disease state in animal models. Taken together, these data support continued preclinical development of Organovo's 3D bioprinted liver tissue for therapeutic use."

"The data show that the approach of delivering a 3D bioprinted tissue patch directly to the liver offers great promise in solving the engraftment and integration issues that have held back many cell and gene therapy attempts at these diseases," said Dr. David Brenner, vice chancellor of Health Sciences and dean of the School of Medicine at UC San Diego, who is also an advisor to Organovo. "We're encouraged by these solid early results, and are eager to see this work advance to the next stages. UC San Diego's ability to leverage translational research to understand and redress disease progression is one of the many reasons we're ideally suited for this kind of collaboration."

Focusing first on pediatric inborn errors of metabolism, Organovo intends to submit an Investigational New Drug ("IND") application to the U.S. Food and Drug Administration ("FDA") for its therapeutic liver tissue in calendar-year 2020. In the next 12 months, the Company expects to optimize its final liver tissue design and continue pre-GLP studies, including efficacy, safety and dosing studies in small animal disease models for IEMs. Organovo is also seeking orphan designation in the U.S. and will partner with contract research organizations ("CROs") to define and scope IND enabling studies.

The Company's posters are as follows:

Title: Long-Term Performance of Implanted Bioprinted Human Liver Tissue in a Mouse Model of Human Alpha-1 Antitrypsin Deficiency

Date: Saturday, October 21, 5:30 - 7:00 pm - Hall D

Poster: 805

Title: Modeling NAFLD Using 3D Bioprinted Human Liver Tissue

Date: Monday, October 23, 12:30 - 2:00 pm - Hall D

Poster: 1963

About Organovo Holdings, Inc.

Organovo designs and creates functional, three-dimensional human tissues for use in drug discovery, clinical development, and therapeutic applications. The Company develops 3D human tissue systems through internal research programs and in collaboration with pharmaceutical, academic and other partners. Organovo's 3D human tissues have the potential to transform the drug discovery process, enabling treatments to be developed more effectively and with greater relevance to performance in human trials and commercialization. The Company's ExVive™ Human Liver and Kidney Tissues are used in high-value drug profiling, including compound screening in disease models, toxicology, target and marker discovery/validation, and other drug testing. The Company is also advancing a preclinical program to develop liver therapeutic tissues for critical unmet medical needs, including certain life-threatening pediatric diseases. In addition to numerous scientific publications, the Company's technology has been featured in The Wall Street Journal, Time Magazine, The Economist, Forbes, and numerous other media outlets. 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; the Company's ability to successfully complete additional preclinical studies, development activities and clinical trials for its therapeutic liver tissue; and the Company's development and regulatory plans and timeline. 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 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 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 successfully complete the contracts and recognize the revenue represented by the contracts included in its previously reported total contract bookings and secure additional contracted collaborative relationships; 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; the risk of further adjustments to the Company's preliminary revenue results for the second quarter of fiscal 2018; the Company's ability to control the costs and to achieve the expected operational benefits and long-term cost savings of its previously announced restructuring plan; and the Company's ability to meet its fiscal year 2018 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 June 7, 2017. 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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