



## Organovo Presents New Preclinical Data on 3D Bioprinted Human Liver Tissues at World Advanced Therapies and Regenerative Medicine Congress

May 18, 2017

SAN DIEGO, May 18, 2017 (GLOBE NEWSWIRE) -- Organovo Holdings, Inc. (NASDAQ:ONVO) ("Organovo"), a three-dimensional biology company focused on delivering scientific and medical breakthroughs using its 3D bioprinting technology, 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 was presented at the World Advanced Therapies and Regenerative Medicine Congress in London by Benjamin Sheperd, Ph.D., Director of 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 data from promising early studies in an established model for alpha-one-antitrypsin deficiency. 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 sustained functionality of the bioprinted cellular organization through 60 days post-implantation, a significant increase in duration from the Company's first preclinical studies, which demonstrated functionality through 28 days. Importantly, these results demonstrate a significant increase in the reported duration of transplanted human hepatocyte synthetic function, and suggest that synthetic function is improved in the animal disease model. Pathologic evaluation of diseased animals receiving transplanted bioprinted liver tissues suggests an improvement in liver health versus non-treated, control animals.

"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 is advancing novel therapeutic solutions 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 increased durability of the liver tissue and strong early evidence of successfully impacting the disease state in animal models. The robust presence of key human metabolic enzymes, which we previously disclosed, is also a critical step in demonstrating the capability of this tissue to treat IEMs, a key indication we are targeting. Taken together, these data support continued preclinical development of Organovo's 3D bioprinted liver tissue for therapeutic use."

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 18 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 will also seek orphan designation in the U.S. at the appropriate time and partner with contract research organizations ("CROs") to define and scope IND enabling studies.

### About Organovo Holdings, Inc.

Organovo designs and creates functional, three-dimensional human tissues for use in medical research and therapeutic applications. The Company develops 3D human tissue models through internal development and in collaboration with pharmaceutical, academic and other partners. Organovo's 3D human tissues have the potential to accelerate the drug discovery process, enabling treatments to be developed faster and at lower cost. The Company's ExVive Human Liver and Kidney Tissues are used in toxicology and other preclinical drug testing. The Company also actively conducts early research on specific tissues for therapeutic use in direct surgical applications. 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](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. 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; and the Company's ability to meet its fiscal year 2017 outlook and/or its long-range 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 9, 2016 and its Quarterly Report on Form 10-Q filed with the SEC on February 9, 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.*

Investor Contact:

Steve Kunszabo  
Organovo Holdings, Inc.

+1 (858) 224-1092  
[skunszabo@organovo.com](mailto:skunszabo@organovo.com)

Press Contact:

Jessica Yingling  
Little Dog Communications  
+1 (858) 344-8091  
[jessica@litldog.com](mailto:jessica@litldog.com)



Organovo, Inc.