



Organovo Presents First Preclinical Data on 3D Bioprinted Human Liver Tissues at TERMIS-Americas Meeting

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Results demonstrate clinical promise for bioprinted tissues

SAN DIEGO, Dec. 13, 2016 (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, is presenting the first data showing survival and sustained functionality of its 3D bioprinted human liver tissue when implanted into animal models. This data is being presented at the TERMIS-Americas Meeting in San Diego.

"With a critical shortage of donor organs and few alternatives to transplantation, Organovo is using its 3D bioprinting technology to develop novel therapeutic tissues for direct surgical implantation," said Eric Michael David, M.D., J.D., chief strategy officer and executive vice president of preclinical development, Organovo. "Our preclinical data show rapid vascularization and tissue engraftment, and evidence of function and durability of our 3D bioprinted human liver tissue over several weeks. Most importantly, we see evidence of stable production of key human liver proteins in the animal bloodstream, and tissue staining for key human metabolic enzymes. The presence of these enzymes provides an important first step in demonstrating the capability of this tissue to treat inborn errors of metabolism, a key indication we are targeting."

Organovo implanted its 3D bioprinted human liver tissue patches onto the livers of NOD/SCID mice. The tissue was composed of human hepatocytes and select non-parenchymal cells. Function of the 3D bioprinted human liver tissue patches was seen via detection of human albumin, alpha-1-antitrypsin and fibrinogen in the circulating blood of the mice as early as seven days and for at least 28 days post-implantation. Histopathologic evaluation of the implanted therapeutic tissue revealed retention of the bioprinted cellular organization through 28 days post-implantation, with robust staining for key human metabolic enzymes associated with inborn errors of metabolism, such as Fumarylacetoacetate Hydrolase (FAH) deficiency and Ornithine Transcarbamylase (OTC) deficiency. The tissues remained intact on the animal liver and were well tolerated by the animals. Taken together, these data support further preclinical development of Organovo's 3D bioprinted liver tissue for therapeutic use.

Focusing first on acute-on-chronic liver failure and pediatric inborn errors of metabolism, both indications where a bioprinted liver patch may show therapeutic benefits, 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 three to five years. The total addressable market opportunity for these initial indication areas exceeds \$3 billion in the U.S. As appropriate, Organovo will pursue breakthrough therapy designation, clinical development outside the United States, and other opportunities to help accelerate time to market.

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.

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 market acceptance of the Company's products and services; the Company's business, research, product development, regulatory approval, marketing and distribution plans and strategies; 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 November 3, 2016. 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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