

Organovo and Roche Researchers Publish Data Demonstrating Superiority of 3D Bioprinted Human Liver Tissues in Assessing Drug-Induced Toxicity

July 11, 2016

SAN DIEGO, July 11, 2016 (GLOBE NEWSWIRE) -- Organovo Holdings, Inc. (NYSE MKT:ONVO) ("Organovo"), a three-dimensional biology company focused on delivering scientific and medical breakthroughs using its 3D bioprinting technology, today announced a publication in the scientific journal, <u>PLOS One</u>, which demonstrates the superiority of Organovo's 3D bioprinted human liver tissues to effectively model drug-induced liver injury and distinguish between highly-related compounds with different toxicity profiles.

Using Organovo's 3D bioprinted human liver tissues, researchers from Organovo and Roche Pharmaceutical Research and Early Development ("Roche") were able to detect significant dose-dependent toxicity of trovafloxacin at clinically relevant doses, compared to levofloxacin, a structurally related, but non-toxic compound. The hepatotoxic potential of trovafloxacin was not originally identified by traditional preclinical tests including animal studies. Trovafloxacin is a third-generation anti-infective drug that was withdrawn from the market one year following its approval due to liver failure and death in a small proportion of patients. Deborah G. Nguyen, Ph.D., Senior Director of Research & Development, was Organovo's lead author for the publication.

"This publication clearly shows the outstanding performance of Organovo's 3D bioprinted human liver tissues when compared to traditional preclinical tests in replicating human drug response at the tissue level," said Dr. Sharon Presnell, chief scientific officer, Organovo.

Drug-induced liver injury is a major cause of late-stage clinical failures and post-market drug withdrawals. Existing preclinical tests include conventional 2D cell culture models, which lack longevity and cannot replicate the complex cell-cell interactions and environment of human tissue. Animal models can miss compounds that are toxic in humans because of species variations and other factors.

"Organovo's bioprinting technology creates an *in vitro* system comprising multiple liver cell types in a defined spatial architecture that can be used over time to gather both histopathological and biochemical data for preclinical toxicity testing," explained Dr. Presnell. "Our durable and reproducible model can also be used to measure cell-type specific responses and investigate toxicity mechanisms to develop alternative solutions."

Organovo's 3D bioprinted human liver tissues are composed of patient-derived parenchymal (hepatocyte) and non-parenchymal (endothelial and hepatic stellate) cell populations. In addition, the Company's 3D bioprinting technology creates tissues that are both spatially patterned and three-dimensional. This solution allowed researchers to perform histologic analyses in this study that revealed distinct intercellular hepatocyte junctions, CD31+ endothelial networks, and desmin-positive, smooth muscle actin-negative quiescent stellates. Unlike 2D cell cultures, Organovo's tissues maintained metabolically relevant levels of ATP and albumin and drug-induced enzyme activity of cytochrome P450s for more than four weeks in culture.

Dr. Presnell concluded, "This data set clearly supports the use of Organovo's 3D bioprinted human liver tissues in preclinical testing for drug-induced liver toxicity to potentially reduce the risk of toxic drugs reaching patients and avoid costly late-stage clinical failures."

The publication entitled, "Bioprinted 3D primary liver tissues allow assessment of organ-level response to clinical drug induced toxicity in vitro," was published online on July 7 and can be found here: http://iournals.plos.org/plosone/article?id=10.1371/journal.pone.0158674

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 disease models through internal development and in collaboration with pharmaceutical and academic 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 recently launched its initial product of the planned exVive3D portfolio offering, the exVive3D Human Liver Tissue for use in toxicology and other preclinical drug testing. Additional products are in development, with the anticipated release of the exVive3D Human Kidney Tissue scheduled for the third quarter of calendar year 2016. 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 medical research and practice. 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. 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. 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

Press Contact:

Jessica Yingling Little Dog Communications +1 (858) 480-2411 jessica@litldog.com



Organovo, Inc.