Organovo Publishes Data Describing Physiology of 3D Bioprinted Human Kidney Tissues for Drug Toxicity Testing

February 21, 2017

Organovo also celebrates positive review of Organovo's 3D bioprinted human liver tissue from industry leaders

SAN DIEGO, Feb. 21, 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 announced the publication of data in Frontiers in Physiology showing the company's 3D bioprinted proximal tubule tissue model exhibits key characteristics of renal physiology that allow for *in vitro* kidney toxicity testing.

"Traditional preclinical models often fall short in their ability to inform clinical outcomes accurately, largely due to the limited functionality of simple *in vitro* models and species differences," said Dr. Sharon Presnell, chief scientific officer, Organovo. "Our newly published data demonstrate that Organovo's 3D bioprinted human kidney tissue has great potential to assess the toxic effects of compounds and the development and progression of complex, multicellular processes such as fibrosis."

Key findings and attributes described in the publication include the following:

- Immunohistochemical characterization showing tight junction formation between epithelial cells, polarized expression of transporters that regulate excretion and reabsorption of compounds, an extensive microvascular network, and deposition of endogenous extracellular matrix in the interstitium;
- Proof-of-concept study for demonstrating induction of toxicity following treatment with a nephrotoxin cisplatin, including a loss of tissue viability and epithelial cell function in a dose-dependent fashion. This effect was blocked by cimetidine, a compound that prevents cisplatin uptake via the transporter OCT2; and
- Induction of tubulo-interstitial fibrosis in this model via administration of TGF-beta, with tissue response verified via gene expression analysis and histological examination of excess extracellular matrix deposition.

In addition to the kidney publication, the Company noted a recent article published in ILAR Journal. The publication explores new technologies that could reduce both dependency on animal models and occurrence of liver toxicity in clinical trials. The article, written by scientific executives and experts from the Food & Drug Administration ("FDA"), Merck & Co., Inc and LifeNet Health, provides a thorough review of human tissue models and how they can accelerate drug development across all discovery stages, including Organovo's 3D bioprinted liver model.

The authors reference Organovo's technology as a "significant innovation in the study of drug-induced liver injury, as it addresses many of the shortcomings associated with traditional *in vitro* culture models and animal models." They also state that 3D bioprinted tissues "exhibit a broad range of highly differentiated *in vivo* like features and functions."

The authors reference results from Organovo's drug-induced liver injury studies that have shown "very good reproducibility and concordance with observed outcomes *in vivo* at the functional and histological levels" and that treatment of the bioprinted human liver model with known fibrotic agents "mimicked closely that of patient liver samples with drug-induced fibrosis."

"Both liver and kidney drug toxicities are significant challenges for pharmaceutical companies working to advance safe and effective therapeutics," said Mr. Keith Murphy, CEO, Organovo. "Previous validation data of our 3D bioprinted human liver tissue, combined with the data published in the peer-reviewed journal, Frontiers of Physiology, on our 3D bioprinted kidney proximal tubule tissue, clearly show that Organovo's technology can address the unmet needs of our pharma customers and partners by providing timely, cost-effective, and more accurate human tissue models for evaluating drug toxicity and drug-induced fibrotic disease."

Organovo's publication titled "3D Proximal Tubule Tissues Recapitulate Key Aspects of Renal Physiology to Enable Nephrotoxicity Testing," was published online on February 15, 2017 and can be found on the journal's website: http://journal.frontiersin.org/article/10.3389/fphys.2017.00123/abstract

The review titled "The Promise of New Technologies to Reduce, Refine, or Replace Animal Use while Reducing Risks of Drug Induced Liver Injury in Pharmaceutical Development," was published December 31, 2016 and can be found on the journal's website: https://academic.oup.com/ilarjournal/article-abstract/57/2/186/2806701/The-Promise-of-New-Technologies-to-Reduce-Refine

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 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.

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