



Organovo Data Presented at Digestive Disease Week (DDW2024) Demonstrating Potential for FXR314 as Combination Therapy with Tofacitinib for Inflammatory Bowel Disease

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SAN DIEGO, May 21, 2024 (GLOBE NEWSWIRE) -- Organovo Holdings, Inc. (Nasdaq:ONVO), a clinical stage biotechnology company focused on developing novel treatment approaches in inflammatory bowel disease (IBD) including ulcerative colitis, today announces data from a poster presented at Digestive Disease Week (DDW2024) demonstrating the potential of the Company's lead clinical-stage compound, FXR314, in combination with tofacitinib for treating inflammatory bowel disease (IBD) using 3D models and preclinical models. DDW2024 is being held in Washington, D.C. May 18-21, 2024.

The poster, titled, "Combination therapy of the FXR agonist FXR314 with tofacitinib in models of inflammatory bowel disease" was presented on Saturday May 18, 2024, in the session "Translational application of intestinal stem cells and organoid models".

"The study highlights the synergistic benefits of combining the Company's non-steroidal, non-bile acid FXR agonist with the JAK inhibitor tofacitinib, supporting the notion of FXR314 as both a monotherapy and as part of a combination approach in IBD", said Dr. Fabrice Piu, Vice President of Research and Development. Key findings showed that FXR314 and tofacitinib improved various measures of intestinal barrier function, inflammation, and fibrosis at optimal concentrations. Further, when combined at sub-eficacious concentrations, FXR314 and tofacitinib combined resulted in further improvements. In addition, FXR314 alone improved measures of colon health and colon histopathology similarly to approved IBD therapies tofacitinib and IL-12/23 antagonist.

Investigators arrived at these conclusions in two ways. The first used Organovo's proprietary 3D IBD model in which multiple cell types derived from IBD patients (either Crohn's disease or ulcerative colitis) are co-cultured. The researchers evaluated target engagement, epithelial barrier integrity, inflammation, and fibrosis in the 3D IBD model using a variety of functional assays. The other approach made use of the adoptive T-Cell transfer model, a well-accepted and predictive preclinical model of colitis, where the effects of combining FXR314 and tofacitinib were evaluated in the treatment paradigm.

"We believe strongly in the opportunity with regard to FXR314 in monotherapy in IBD, but these results, our first in a combination therapy approach, are exciting," stated Keith Murphy, Organovo's Executive Chairman. "These results further bolster our belief in the potential of FXR314 in combination therapy, and such data will be beneficial both in terms of potential combination development and also when used in monotherapy. As these data at the prestigious Digestive Disease Week show, FXR314 has the potential to show positive results in future clinical studies when used with an already prescribed biologic by improving a patient's outcomes relative to the use of the already prescribed therapy alone."

About Organovo

Organovo is a clinical stage biotechnology company that is developing drugs that are demonstrated to be effective in three-dimensional (3D) human tissues as candidates for drug development. The company's lead molecule, FXR314, is on the path for Phase 2 investigation in inflammatory bowel disease and has potential application in metabolic liver disease and oncology. The company has proprietary technology used to build 3D human tissues that mimic key aspects of native human tissue composition, architecture, function, and disease. For more information visit Organovo's website 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. These risks and uncertainties 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 July 14, 2023, as such risk factors are updated in its most recently filed Quarterly Report on Form 10-Q filed with the SEC on February 8, 2024 and the Registration Statement on Form S-1 (File No. 333-278668), as amended. 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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